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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,985	11/28/2000	Philip Michael Savage	674544-2001	8380

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EXAMINER	
VANDERVEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,985	SAVAGE, PHILIP MICHAEL	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2004 and 22 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-9 and 11-75* is/are pending in the application.

4a) Of the above claim(s) *19-22 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,9,11-18,23-49 and 52-75* is/are rejected.

7)☒ Claim(s) *7,8,50 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01272004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation-in-part of Application Serial Number PCT/GB99/01764.

Claims 2, 5, 10 have been canceled.

New claims 30-75 have been added.

Claims 1, 3, 4, 6-9 and 11-75 are currently pending.

Claims 19-22 and 25 stand withdrawn as being drawn to a non-elected invention.

Election/Restrictions

Applicant's election with traverse of the species tumor cells, malignant cells or leukemia cells in the reply filed on January 22, 2004 is acknowledged. The traversal is on the ground(s) that there a disclosed relationship between the species because they all constitute target cells that can be bound by the complex of the claimed invention. This is not found persuasive because each of the different species is identified by a different type of cell from a unique source, requiring a separate search of the antigenic peptides derived from the cell type and the surface antigens to which the complex may bind.

However, upon further review, the **species requirement is hereby withdrawn**.

Accordingly, claims 1, 3, 4, 6-9, 11-18, 23, 24 and 26-75 are the subject of examination in the present Office Action.

Response to Arguments

1. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4, 6, 9, 11-18, 23, 24, 25-39, 46-49, 52-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

The claims are drawn to a complex comprising a complex comprising an MHC class I molecule joined to a linking polypeptide specific for a target cell, wherein the MHC class I molecule and the linking peptide are joined to one another via a coupling system comprising a first small molecule and a second small molecule.

The scope of the claims, drawn to a complexes where the coupling system comprises "small molecules" to the immunogen, includes in scope a number of embodiments for which there is no sufficient written description in the specification. The term "small molecule" is a broad term encompassing a plethora of organic and non-organic molecules and is not defined in the instant specification is such a manner as to apprise the artisan of the scope of small molecules encompassed by the claims or that Applicant had possession of a representative number of species of "small molecules." The specification is limited in its description of small molecules, reciting only, "The coupling system may comprise a two- or three-step chain of well-characterised paired small molecules, joined to the antibody and the Hl.A class l molecule so as to form a stable bridge between the two. Examples of paired small molecules which might be used inthis connection include (but are not limited to) biotin and avidin/streptavidin [...] and calmodulin and calmodulin binding peptides [...]" at lines 1-8 of page 7, for example. *Vas-Cath Inc. v. Mahurkar* ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). It is respectfully submitted that the instant specification does not describe a sufficient number of species to provide full descriptive support of the genus encompassing all such molecular adjuvants.

Therefore only the disclosed species of "small molecules," namely the paired small molecules biotin - avidin/streptavidin and calmodulin - calmodulin binding peptides, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

3. Claims 40-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The monoclonal antibodies C46, 85A12, H17E2, HMFG1, W14, 1F5, and 225.28s recited in claims 40 and 43 are essential to the claimed invention. The reproduction of hybridomas producing a specific antibody is an extremely unpredictable event. The hybridomas producing each of C46, 85A12, H17E2, HMFG1, W14, 1F5, and 225.28s, disclosed on page 6 of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the hybridoma, and it is not apparent if the hybridoma is readily available to the public. If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridoma has been deposited under the Budapest Treaty and that the hybridoma will be **irrevocably** and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent**, whichever is longer. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and CURRENT address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from Applicant to the depository coupled with corroboration that the deposit is identical to the biological material

described in the specification and in the Applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 9, 28, 29, 40-45, 66, 68, 74 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 49 are indefinite in reciting that the linking peptide of the base claim is directly attached to the linking peptide. The base claim in each case requires that the linking peptide is joined to the MHC class I molecule via a coupling system comprising a first "small molecule" that interacts with a second "small molecule" to form a stable bridge between the moieties. Accordingly, there is no antecedent basis for the recitation of a direct linkage between the MHC class I and linker moieties.

Claims 9 and 52 are indefinite in the recitation of a recombinant protein comprising an MHC class I moiety and a moiety comprising the attaching means. The base claim in each case requires that the linking peptide is joined to the MHC class I molecule via a coupling system comprising a first "small molecule" that interacts with a second "small molecule" to form a stable bridge between the moieties. Accordingly, there is no antecedent basis for the recitation of a recombinant protein comprising both the MHC class I and linker moieties because the required intervening "small molecules" cannot be encoded as part of a recombinant protein.

Claims 28, 29, 45, 74 and 75 are indefinite in reciting a pharmaceutical pack or kit containing one or more of the pharmaceutical compositions claimed in a base claim. In each case, the base claim is drawn to a single pharmaceutical composition and therefore does not provide adequate antecedent basis for reciting "one or more" of the "compositions."

Claims 66 and 68 are ambiguous and unclear because a multiple dependent claim cannot be dependent upon more than one base claim at a time. The claims should be amended to physivcally incorporate the limitations of at least one of the base claims..

Claims 40-45 are indefinite and ambiguous to recite the laboratory names C46, 85A12, H17E2, HMFG1, W14, 1F5, and 225.28s in claims 40 and 43 to identify the monoclonal

antibodies. The same designation may be used by others as well to designate different cell lines or antiobodies. It is suggested that the corresponding accession or deposit number from an acceptable depository be recited in the claim.

Conclusion

5. Claims 7, 8, 50 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
August 23, 2004

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
8/23/04